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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/009,384	GENNARO ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 October 2007 has been entered.

Claims 1, 11, 16, 17, 18, 19, and 20 have been amended.

2. Claims 1-8 and 11-20 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 1-8 and 11-20 under 35 U.S.C. 112, second paragraph, as being indefinite for peptide identity, is withdrawn in light of the amendment of the claims.

Rejections Maintained

4. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained.

Applicants argue that U.S. Pat. No. 6,087,163, incorporated by reference contains working examples of serologic immunoassays detecting immune responses to *M. tuberculosis* polypeptides.

The examiner has considered applicants' arguments and their support document, i.e., U.S. Pat. No. 6,087,163, but does not find them persuasive. While U.S. Pat. No. 6,087,163 does teach immunoassays in general, it does not teach the specific sequences in the instant claims. Thus, the rejection is maintained because the instant specification teaches merely

computer generated sequenced of *M. tuberculosis* DNA with predicted proteins, but does not teach that the claimed sequences can diagnosis infection with *M. tuberculosis*.

Applicants argue that "segments" are enabled because while some experimentation is required to determine which, if any, segments of the claimed polypeptides retain the required immunogenic properties, the experimentation is not "undue", but routine.

The examiner has considered applicants' argument, but does not find it persuasive because the instant specification does not provide any working examples of the complete polypeptides, nor teach if any of the "segments" would retain the required activity. Thus, if the whole polypeptide does not function as required, it would constitute undue experimentation to determine if any segments would function as required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al (U.S. Pat. No. 5,736,365, 7April1998).

Claim 1 is drawn to an isolated DNA "comprising" a DNA sequence encoding a polypeptide with a sequence of SEQ ID NO:15, 21, 25, 36, 43, or 47. These sequences are *M. tuberculosis* polypeptides.

The use of the phrase, an isolated DNA "comprising" a DNA sequence, reads on the whole genome of *M. tuberculosis*. Thus, Walker et al teach the claimed isolated DNA when they

utilize whole DNA genome of *M. tuberculosis* as a starting material for the probes/primers of their assays (Abstract; Col. 1, lines 30-61; Example 1).

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Horwitz et al (U.S. Pat. No. 5,108,745, 28April1992).

Claim 11 is drawn to an isolated polypeptide with an amino acid sequence selected from a group consisting of the sequence SEQ ID NO:15, 21, 25, 36, 43, or 47. These sequences are *M. tuberculosis* secretory polypeptides.

Horwitz et al teaches isolation of all *M. tuberculosis* secretory polypeptides (Abstract; claims 13-17).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 4, 6, 8, 12, 14, 15, 16, 18, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 12, 15, 16, 18, 19, and 20 recite: "wherein the segments retain specific antigenic properties". It is unclear what is and what is not considered a "specific" antigenic property. Thus, it is unclear what segments are encompassed by this description. Claims 4, 6, 8, and 14 are dependent claims, but do not clarify the issue.

10. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from a rejected claim, i.e., claim 1.

11. Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from a rejected claim, i.e., claim 11.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.


The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

December 31, 2007